

Serial No. 10/602,215
PC 21501B

Please replace all prior claims in the application with the following:

Claim 1 (previously presented): A liquid pharmaceutical composition comprising a gamma-aminobutyric acid (GABA) analog and one or more polyhydric alcohols, each containing 2 to 6 carbon atoms, wherein the one or more polyhydric alcohols comprise about 25% to about 75% weight/volume of the composition and the composition has a pH of about 5.5 to about 7.0.

Claim 2 (previously presented): The composition according to claim 1, wherein the one or more polyhydric alcohols each contains 3 to 5 carbon atoms.

Claim 3 (previously presented): The composition according to claim 2, wherein the one or more polyhydric alcohols are selected from the group consisting of: glycerol, xylitol, sorbitol, mannitol, and a mixture of glycerol and xylitol, and wherein the one or more polyhydric alcohols comprise about 40% to about 75% weight/volume of the composition.

Claim 4 (original): The composition according to claim 1, wherein the pH is about 6.0 to about 7.0.

Claim 5 (previously presented): The composition according to claim 1, comprising one or both of: a preservative and a flavor improver, wherein the flavor improver does not contain an aldehyde or keto functionality.

Claim 6 (previously presented): A method for preparing a liquid pharmaceutical composition comprising: adding one or more polyhydric alcohols, each containing 2 to 6 carbon atoms, to water to form a first solution; adding a gamma-aminobutyric acid analog to the first solution to form a second solution; and optionally adjusting the pH of the second solution to about 5.5 to about 7.0 to afford the liquid pharmaceutical composition, wherein the one or more polyhydric alcohols comprise about 25% to about 75% weight/volume of the composition.

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Claim 7 (previously presented): The method according to claim 6, wherein the one or more polyhydric alcohols are a mixture of glycerol and xylitol.

Claim 8 (previously presented): The method according to claim 6, wherein the pH of the composition is about 6 to about 7.

Claim 9 (previously presented): A liquid pharmaceutical composition comprising a first component, the first component comprising a powder mixture of a gamma-aminobutyric acid (GABA) analog and one or more solid polyhydric alcohols and a second component comprising a liquid base, wherein the first and second components are combined to afford the liquid pharmaceutical composition in which the one or more polyhydric alcohols comprise about 25% to about 75% weight/volume of the composition.

Claim 10 (previously presented): A method for preparing a liquid pharmaceutical composition, the method comprising: mixing a gamma-aminobutyric acid (GABA) analog with a first solid polyhydric alcohol to afford a powder mixture; mixing a second polyhydric alcohol with a sweetener and a flavor in water to afford a liquid base; and adding the powder mixture to the liquid base to afford the liquid pharmaceutical composition, wherein the first and second polyhydric alcohols may be the same or different and together comprise about 25% to about 75% weight/volume of the composition.

Claim 11 (original): The method according to claim 10, wherein the GABA analog is gabapentin or pregabalin.

Claim 12 (original): The composition according to claim 1 or claim 9 wherein the GABA analog is gabapentin or pregabalin.

Claim 13 (previously presented): The composition according to claim 1 or claim 9 wherein the composition has less than 0.5% by weight of the corresponding lactam of the GABA analog.

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Claim 14 (currently amended): A liquid pharmaceutical composition comprising gabapentin or pregabalin, water, and one or more polyhydric alcohols, each containing 2 to 6 carbon atoms, the composition having a pH of about 5.5 to about 7.0 and containing less than 0.5% ~~weight/weight~~ ~~weight/volume~~ of gabapentin lactam or pregabalin lactam, respectively, after storage at 2°C to 10°C for 18 months to 2 years, wherein the one or more polyhydric alcohols comprise at least 25% weight/volume of the composition.

Claim 15 (canceled)

Claim 16 (new): A method of treating a subject suffering from a cerebral disease, including epilepsy, faintness attacks, or hypokinesia; cranial trauma, a neurodegenerative disorder, depression, mania, bipolar disorder, anxiety, panic, inflammation, renal colic, insomnia, gastrointestinal damage, incontinence, migraine, or pain, including neuropathic pain, muscular pain, or skeletal pain, the method comprising administering to the subject a therapeutically effective amount of the pharmaceutical composition according to claim 1 or claim 13.

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